DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

Medtronic, Inc.
Jessica Sixberry
Principal Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K143073
Trade/Device Name: Affinity NT Oxygenator, Affinity NT Oxygenator with Trillium Biosurface, Affinity NT Oxygenator with Carmeda Biosurface
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: February 13, 2015
Received: February 18, 2015

Dear Ms. Sixberry,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143073

Device Name

Affinity NT Hollow Fiber Oxygenator

Indications for Use *(Describe)*

Model 511:
The Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Model CB511:
The Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber with Carmeda BioActive Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Model 511T:
The Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber with Trillium Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: March 18, 2015

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

Contact Person: Jessica Sixberry
Principal Regulatory Affairs Specialist
Phone: (763) 514-9849
Fax: (763) 367-8360
Email: jessica.m.sixberry@medtronic.com

Device Name and Classification:

Trade Name:	Affinity NT Oxygenator Uncoated or with Carmeda® BioActive Surface or with Trillium® Biosurface
Common Name:	Oxygenator
Classification Name:	Cardiopulmonary bypass Oxygenator
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II

Predicate Devices

Medtronic Affinity Oxygenator (K932252)
Medtronic Affinity Oxygenator with Trillium Biosurface (K973760)
Medtronic Affinity Oxygenator with Carmeda BioActive Surface (K000430)

Device Description

The Medtronic Affinity NT Hollow Fiber Oxygenator is a single use gas exchange device with plasma resistant fiber. It is designed to have the blood flow outside the fiber and includes an integral heat exchanger. The oxygenator is available uncoated or bonded on its blood contacting surfaces with either Carmeda BioActive Surface or Trillium Biosurface. The device is single-use, nontoxic, nonpyrogenic, and supplied sterile for clinical use.

The Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Affinity NT Oxygenator is designed to be an integral part of the cardiopulmonary heart lung bypass circuit for use during cardiac surgery. Blood that comes from the patient is delivered through a blood pump to the oxygenator and other auxiliary devices, and back to the patient.

The purpose of this 510(k) Notification was to notify the FDA of an alternate material formulation for the luer caps used on the access port and the sample port as well as report previous changes on the Affinity NT Oxygenator models identified in the table below.

Models	**Description**
511	Affinity NT Oxygenator
CB511	Affinity NT Oxygenator with Carmeda BioActive Surface
511T	Affinity NT Oxygenator with Trillium Biosurface

Indications for Use

The Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (with Carmeda BioActive surface or Trillium Biosurface) is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Comparison to Predicate Devices

The Affinity NT Oxygenators have the same intended use, design and materials, and principles of operation and technology when compared to the predicate Affinity Oxygenators (including previously implemented changes).

- Intended Use: The intended use is the same as the predicate devices.
- Design: The design is the same as the predicate devices.
- Materials: The materials of the Affinity NT Oxygenator are the same or equivalent to the materials used in the predicate devices.
- Principles of Operation and Technology: The principles of operation are the same as the predicate devices.
- Performance: The performance of the device is the same as the predicate device.

Summary of Performance Data

Bench testing was used to verify the performance characteristics of this device. In addition, real-time aging testing for devices incorporating the previously implemented changes was completed and supports substantial equivalence. Clinical testing was not required to establish substantial equivalence.

The following performance tests were conducted:

Testing		Description	Result
Subject of 510(k)	Biocompatibility	Ensures alternate material for the luer cap is biocompatible according to ISO 10993-1, externally communicating, circulating blood contact, limited duration	Pass
	Positive Pressure Integrity Testing	Ensures luer caps made with the alternate material maintains appropriate seal on the device ensure the device does not leak	Pass
Previously Implemented Changes (real time aging)	Gas Transfer (oxygen and carbon dioxide)	Demonstrates the devices transfer gas to specification	Pass
	Pressure Drop (Blood and Gas)	Demonstrates the devices meet pressure drop requirements	Pass
	Plasma Breakthrough	Demonstrates the devices meet Plasma Breakthrough requirements	Pass
	Blood Trauma (hemolysis, Platelets, White Blood Cells)	Demonstrates the devices meet Blood Trauma requirements	Pass
	Pressure Integrity	Demonstrates the devices meet Pressure Integrity requirements	Pass
	Heat Exchanger Performance	Demonstrates the devices meet the heat exchanger efficiency requirements	Pass
	Coating Testing	Coating testing demonstrates that the coated devices meet the coating requirements	Pass

Conclusion

Medtronic has demonstrated that the Affinity NT Oxygenators are substantially equivalent to the predicate devices based upon design, test results, and indications for use.